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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSCU-128/00US 027060-2694	1401

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
07/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,487	RIOUX ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,17-20,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,17-20,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/7/08 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,19,20,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard (WO 97/27898) in view of Lee et al. (5123917). Evard et al. illustrates (Fig. 2') a coil segment with a middle portion **14** spaced from the proximal and distal windings and has a diameter less than the proximal and distal ends. Claim 1 includes a product by process limitation "unitarily formed" and should be noted that the product itself does not depend on the process for making it. Evard is considered to be unitarily formed. Evard et al. disclose a covering or what can be interpreted as "webbing" such that the entire device is encapsulated or *covered* by the covering, page 33, lines 8-13. It can be interpreted from the disclosure of Evard on page 14, lines 22-25 that these coverings inhibit ingrowth of body tissue. Evard also discloses the coil can be a

biocompatible wire made from steel or nickel titanium, page 34, lines 1-3. The Examiner is also interpreting the limitation "webbing between the windings" to be present in the Evard device since the covering is over the windings, it can be considered between the windings. The stent device is capable of being positioned coaxially within the body lumen of a patient. The apparatus is capable of use and of sufficient strength to maintain the urethra open. Evard does disclose the length of the device can vary and is chosen to accommodate the need of the patient (page 19, lines 7-9, page 33, lines 35-37, page 40, lines 1-7), thus the coil segment can be configured to extend from near the opening of a patient's bladder through the urethra and terminate before the sphincter. However, Evard fails to disclose the distance between the windings to be at least about 0.5mm or that the webbing or covering is inner and outer layers adhered together or the specific cross sectional area of the wire. Lee et al. teach a spacing between coils to be greater than 0.5mm (col. 5, lines 41-43) when positioned in the vessel. Lee et al. also teach (Figs. 3,4) a stent with coils **30** having both inner **10** and outer **20** layers of polymer encapsulate the coil body for physical barrier of blood, col. 3, lines 65-68. Lee also teaches to have the polymer layers adhered together, col. 5 lines 29,30. Lee additionally teaches a cross-sectional area of the wire that falls within the claimed range of 0.0079mm^2 to 7.1 mm^2 (col. 5, lines 59-61). It would have been obvious to one of ordinary skill in the art to bond or adhere inner and outer polymer layers on the coil stent and space coil windings at least about 0.5mm and use a wire having a cross-sectional area within 0.0079mm^2 to 7.1 mm^2 as taught Lee et al. for the

device of Evard such that the desired spacing between windings for flexibility can be established within the layers.

Claims 6,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. '917 as applied to claim 1 and further in view of Yachia et al. (5246445). Evard as modified by Lee et al. is explained supra. However, Evard in view of Lee do not disclose the distal and proximal portions of the coil segment include hooks. Yachia et al. teach (Fig. 1a) a stent with hooks **3** at both the proximal and distal ends of the coil body for connection to a delivery system, col. 6, lines 13-16. It would have been obvious to one of ordinary skill in the art to incorporate hooks at both proximal and distal ends of a stent as taught Yachia et al. in the device of Evard as modified by Lee et al. such that the vessel apparatus does not dislodge from the instrument used to implant it. The addition of the hooks enables the surgeon to precisely place the vessel-opening device in its location without the apparatus being displaced during insertion.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. '917 as applied to claim 1 and further in view of Hachtman et al. (5645559). Evard as modified by Lee et al. is explained supra. Evard does disclose the polymer is elastomeric (page 33, lines 5,6) and that silicone layers can be placed on stents, page 17, lines 21-24. However, Evard in view of Lee do not disclose the polymer being a *low durometer* silicone within the range of 0-60D. Hachtman et al. teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of

fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the silicone on Evard's stent as modified by Lee et al. such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

Claims 17,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. '917 as applied to claim 1 and further in view of Thorud et al. (6019779). Evard as modified by Lee et al. is explained above. However, Evard in view of Lee fail to explicitly disclose a longer coil such that there are multiple windings and spaces there between. Thorud et al. teach (Figs. 2,3) a coil device for a lumen having multiple windings with the distance between the spaced windings being about 0.5mm, col. 5, lines 3-5. It would have been obvious to one of ordinary skill in the art to lengthen the coil device of Evard in view of Lee such that the spacing between windings is about 0.5mm with a winding located at the distal end as taught by Thorud et al. and provide a greater length stent for keeping a passageway open that has larger distance to span.

Response to Arguments

Applicant's arguments filed 5/7/08 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The combination only involves simple teachings well within the skill of a normal artisan in the art. We must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. In this case, the results would be predictable since it is known that modifying the spacing have certain results, for example, if the desire of the application of the device requires more coverage or support, then one of ordinary skill would space the windings closer. On the other hand if the application of use does not require extensive coverage and needs more flexibility, then one of ordinary skill in the art would space the windings further apart. Applicant's claims are nothing more than the predictable outcome where modifying the spacing between coils to be separated by at least 0.5mm as taught by Lee clearly provides a result capable of being achieved with the Evard device. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l. Co. v. Teleflex Inc.,* 127 S.Ct. at 1742, 82 USPQ2d at 1397.

Applicant additionally argues the combination of Thorud with Evard and Lee would not result in a functionable device for its intended purpose. However, Lee nor Evard disclose that the spacing is not permitted to be uniform. Thus, the teaching of Thorud to have spacings at the ends and central section to be about 0.5mm does not

teach away from the disclosures of Lee and Evard. Applicant argues the modified device would not have "sufficient strength" to function. However, this is a relative function and the properties of the coil can still impart sufficient strength even if the spacing of the coils is changed. Arguments are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (8:30-5pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

/Brian E Pellegrino/
Primary Examiner, Art Unit 3738